

First Action Interview Pilot Program Pre-Interview Communication	Application No. 10/584,816	Applicant(s) REIDENBERG ET AL.	
	Examiner Kevin S. Orwig	Art Unit 1611	Page 1 of 2

-The MAILING OR NOTIFICATION DATE of this communication appears on the cover sheet with the correspondence address -
THE SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE **ONE MONTH OR THIRTY (30) DAYS**, WHICHEVER IS LONGER, FROM THE MAILING OR NOTIFICATION DATE OF THIS COMMUNICATION.

This time period for reply is extendable under 37 CFR 1.136(a) for only ONE additional MONTH.
This communication constitutes notice under 37 CFR 1.136(a)(1)(i).

Applicant must, within the time period for reply, file: (1) A letter requesting not to have a first action interview; (2) A reply under 37 CFR 1.111 waiving the first action interview and First Action Interview Office Action; or (3) An Applicant Initiated Interview Request Form (PTOL-413A) electronically via EFS-Web, accompanied by a proposed amendment or arguments, and schedule the interview within 2 months from the filing of the request. A failure to respond to this communication will be treated as a request not to have an interview. If applicant waives the First Action Interview Office Action, the instant Pre-Interview Communication is deemed the first Office Action on the Merits. The next subsequent Office action may be made final if appropriate. See MPEP 706.07(a).

Disposition of Claims

- 3) ☒ Claim(s) 1-13, 18, 19, 21-23, 31, and 32 is/are pending in the application.
3a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 4) ☐ Claim(s) _____ is/are allowed.
- 5) ☒ Claim(s) 1-13, 18, 19, 21-23, 31, and 32 is/are rejected.
- 6) ☐ Claim(s) _____ is/are objected to.
- 7) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 8) ☒ The specification is objected to by the Examiner.
- 9) ☒ The drawing(s) filed on 27 June 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 10) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 11) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

Contact Information

Examiner's Telephone Number: (571)270-5869
Examiner's Typical Work Schedule: Monday-Friday 7AM-4PM
Supervisor's Name: Sharmila Landau
Supervisor's Telephone Number: (571)272-0614

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____. |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12/26/06, 9/20/07, 8/15/08, 11/12/08, 3/9/09, 12/28/09.</u> | 6) <input type="checkbox"/> Other: _____. |

First Action Interview Pilot Program Pre-Interview Communication				Application No. 10584816	Applicant(s) REIDENBERG ET AL.
				Examiner Kevin S. Orwig	Art Unit 1611
Notification of Rejection(s) and/or Objection(s)					
#	Claim(s)	Reference(s) (if applicable)	Rejection Statutory Basis	Brief Explanation of Rejection	
1	1-13, 18, 19, 21-23, 31, 32		112 2nd	Clms. 1 and 3: "...effective amount..."; clm. 22: "...rubber- like..."	
2	1-13, 18, 19, 21-23, 31, 32	AA, AC, A, B	103(a)	Granger (Ref AA on IDS of 12/26/06) discloses the inventive concept of the claimed invention, but is silent to the particle size of the encapsulated antagonist. However, adjustment of the particle size is not inventive. See further discussion below.	
3	1-13, 18, 19, 21-23, 31, 32	AA, AC, A, B	Double Patenting	10/476601; 11/865387. The selection of the salt/free base form of the active agents is within the purview of the skilled artisan. Moreover the prior art teaches the claimed forms.	

Expanded Discussion/Commentary		
2		In combination with Granger, any of Oshlack (Ref AC on IDS of 9/20/07), Sackler (Ref A on 892), and/or Gale (Ref B on 892) render obvious the optimization of the particle size to the claimed ranges. Additionally Granger recognizes the benefit of making the antagonist difficult to separate from the agonist. Thus, any skilled artisan would appreciate that making the antagonist particles visually indiscernible would accomplish this goal.
DATE:		/Kevin S. Orwig/ Examiner, Art Unit 1611
		/Sharmila Gollamudi Landau/ Supervisory Patent Examiner, Art Unit 1611